

Food and Drug Administration New Orleans District Southeast Region 6600 Plaza Drive, Suite 400 New Orleans, Louisiana 70127

Telephone: 504-253-4519 Facsimile: 504-253-4520

May 30, 2001

## **WARNING LETTER NO. 2001-NOL-26**

## FEDERAL EXPRESS OVERNIGHT DELIVERY

Mr. Orlando Cherenek, Owner Del Rey Enterprises, Inc. 2508 Metairie Lawn Drive Metairie, LA 70002

Dear Mr. Cherenek:

We inspected your firm, located at 2508 Metairie Lawn Drive, Metairie, Louisiana, on May 10, 2001, and found that you have serious deviations from the Seafood HACCP regulations, Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause your smoked herring and salted codfish to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at <a href="http://www.fda.gov">http://www.fda.gov</a>.

## The deviations were as follows:

- You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for smoked herring and salted codfish to control the food safety hazard of pathogen growth.
- You must have sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11(c). Your firm did not maintain sanitation control records for any of the following eight areas of sanitation:
  - 1. Safety of water;
  - 2. Condition and cleanliness of food contact surfaces;
  - 3. Prevention of cross-contamination;
  - 4. Maintenance of hand washing, hand sanitizing and toilet facilities;
  - 5. Protection of food, food packing material, and food contact surfaces from adulteration;
  - 6. Proper labeling, storage, and use of toxic compounds;
  - 7. Control of employees with adverse health conditions; and,
  - 8. Exclusion of pests.

The above deviations were previously brought to your attention on the Form FDA 483s issued at the conclusion of the inspections of March 3, 1999 and July 31, 2000.

These findings are further detailed in the enclosed Form FDA 483 that was discussed with you at the conclusion of the current inspection on May 10, 2001.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your HACCP plan, sanitation monitoring records, and temperature monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your response should be directed to Mark W. Rivero, Compliance Officer, at the above address.

Sincerely,

Carl E. Draper
District Director

**New Orleans District** 

Carl E. Roger

Enclosure: Form FDA 483